SILK PRODUCT INSERT

SILK NONABSORBABLE SURGICAL SUTURES, U.S.P.

DESCRIPTION
Silk is a nonabsorbable, sterile surgical suture composed of an organic protein called fibron. This protein is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae.

Silk surgical suture is braided or twisted and available undyed or dyed black (dogwood extract). Braided sutures are coated with silicone (unless otherwise noted). Silk surgical sutures meet all requirements established by the United States Pharmacopeia (U.S.P.) for nonabsorbable surgical sutures.

INDICATIONS
Silk surgical sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, orthopaedic, and neurological procedures.

ACTIONS
Silk surgical sutures elicit a minimal inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. While silk surgical suture is not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of the suture's tensile strength over time.

CONTRAINDICATIONS
The use of this suture is contraindicated in patients with known sensitivities or allergies to silk.

Because of the gradual loss of tensile strength that may occur over prolonged periods in vivo, silk surgical sutures should not be used wherever permanent retention of tensile strength is required.

WARNINGS
Do not use if package is open or damaged or if the expiration date has been exceeded. Discard open, unused suture. Do not resterilize; resterilization may alter the physical properties of this suture.

Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in a "sharps"container.

Avoid storing product at elevated temperatures. As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.

Users should be familiar with surgical procedures and techniques involving nonabsorbable suture before employing silk suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

PRECAUTIONS
In handling this or any other surgical suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Adequate knot security requires the accepted surgical technique of flat, squared ties with additional throws as warranted by surgical circumstance and experience of the surgeon.

ADVERSE REACTIONS
Adverse effects associated with the use of this device include wound dehiscence, gradual loss of tensile strength over time, allergic response in patients that are known to be sensitive to silk, calculus formation in urinary and biliary tracts when prolonged contact with salt solution such as urine and bile occur, infected wounds, acute inflammatory tissue, and transitory local irritation.

HOW SUPPLIED
Silk suture is available in (USP) sizes 9-0 through 5 (metric size 0.3 – 7) braided or twisted, silicone coated (unless otherwise noted), undyed (white) or dyed black (dogwood extract). The suture is supplied sterile in precut lengths or ligating reels; both non-needle and affixed to various needle types including removable needles; in one, two, or three dozen boxes.

CAUTION
Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

SYMBOL DEFINITIONS
- LOT Lot Number
- Exp. Expiration Date
- Do Not Reuse
- Do Not Resterilize
- Manufacturer
- See Instructions For Use
- Sterilized By Ethylene Oxide
- Sterilized by Gamma radiation
- MDSS GmbH SCHIFFGRABEN 41
  30175 HANNOVER, GERMANY

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